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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,768	05/04/2005	Piero Chiarelli	0002263USU/3061	8171

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
03/23/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,768	CHIARELLI ET AL.	
	Examiner	Art Unit	
	NISSA WESTERBERG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-36 and 38-50* is/are pending in the application.

4a) Of the above claim(s) *46-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-36 and 38-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/4/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments, filed February 4, 2011, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 – 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 34 – 36 and 38 - 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 34 has been amended to include a functional limitation of "thereby avoiding an intense red color from rifaximin at the site of administration". No where in the instant application is the word "administration" used. ¶ [0007], cited by Applicant to support the newly added claim limitation, uses the term "somministration" and does not refer to a lack of color at the place of somministration but rather avoiding an intense red

color "in the neighboring of the place", which seem to indicate not the site of somministration but rather an area surrounding the site somministration.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 34 – 36, 38 – 42 and 44 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios (US 2002/0004065). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 5, 2010 and those set forth below.

Applicant traverse this rejection on the grounds that "local" and "topical" have similar meanings and "transdermal" have a completely different meanings and the instant claims recite local delivery of rifaximin.

This argument is unpersuasive. The claims are drawn to "[a] device for controlled local delivery". In response to applicant's argument that local and transdermal are different routes of drug administration, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicants have not presented any evidence that the transdermal product of the applied art with the structural elements recited in the body of the claim are not capable of providing local delivery.

Applicant also argues that a skilled person would not have considered a document limited to transdermal systems for solving a problem of a nonsystemic antibiotic. A number of references (Annex B – M) are submitted that discuss rifaximin in

various contexts. These documents were in part submitted to support an argument that rifaximin is non-absorbable via transdermal administration. Kanios is absolutely scientifically incorrect and undeniably unreliable. Even if considered, Kanios would teach way from rifaximin in view of its non-systemic absorbability and the skilled person would not have considered the devices enabled.

These arguments are unpersuasive. The majority of the documents relate to the fact that when administered orally, rifaximin does not enter the systemic circulation, due its being ionized at all pH values that are encountered in the gastrointestinal tract (Berlo et al., p 205, col 2, ¶ 1). All references to rifaximin being a non-systemic antibiotic are in conjunction with an oral administration route and thus are of limited relevance to the instant claims and applied art that apply the drug to the skin. When rifaximin is able to enter the systemic circulation by intravenous injection, the drug is detectable in the plasma hours later (Gionchetti et al., p 28, col 2, ¶ 3), indicating that rifaximin can have systemic effects IF the drug is able to gain access to the blood stream. When administered orally, no such absorption occurs and rifaximin is non-systemic. However, oral administration is not the route of either Kanios or the instant claims.

Several of the references do relate to application of rifaximin to the skin and are of greater relevance to the instant case. Applicants' argument is premised on the argument that transdermal compositions must result in systemic concentrations of the drug based on the dictionary definition of transdermal. The Venturini and Berlo references studied serum and blood concentrations of rifaximin after application to the skin and found the amounts to be below the limitation of detection. However, one must

also look at the context in which Kanios uses the term "transdermal" and the scope of their invention, particular since applicant can act as their own lexicographer. Kanios indicates that "any active agent that is capable of producing a pharmacological response, localized or systemic ... is within the contemplation of this invention" (¶ [0056], emphasis added). The therapeutically effective amounts of these agents delivered by the adhesive matrix compositions are "concentrations sufficient to achieve the desired local or systemic effect or result" (¶ [0055], emphasis added). Rifaximin (¶ [0093]) is also among the ansamycin antibacterial active ingredients contemplated for use in the adhesive matrix that provides the zero-order release disclosed by Kanios. That the drug [rifaximin] may not absorb through the skin to enter the systemic circulation is insufficient as Kanios does not require systemic activity for the therapeutic agent present in their transderma delivery system. Application of a definition other that which is used by Kanios to define his own invention does not render his teachings scientifically incorrect and unreliable as alleged by Applicant. When the teachings of Kanios as a whole are considered and his definition of agents to be included in the transdermal delivery device, Kanios is not scientifically incorrect and therefore is reliable because Kanios contemplated the inclusion of drugs with either one or both of local or systemic effects for use in their transdermal drug delivery system.

In regards to the new claim limitation, intense red color at the site of administration or lack thereof is determined by the administration form upon use of the device. As a device with the same structural elements as is recited in the body of the claims is taught by Kanios as is recited by the instant claims, the form of Kanios

necessarily provides for the avoidance of an intense red color at the site of administration.

8. Claim 43 was rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios further in view of Govil et al. (US 4,908,213). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 5, 2010 and those set forth below.

Applicant has not specifically addressed this rejection other than referring to Govil, so the rejection is maintained for the reasons set forth above with regard to Kanios above.

9. Claim 45 was rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios further in view of Wharton et al. (US 6,194,455). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 5, 2010 and those set forth below.

Applicant indicates that Wharton fails to supplement the deficiencies of Kanios. This argument is unpersuasive. As discussed in greater detail above, Kanios is not deficient so Wharton is not required to cure that deficiency.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NISSA WESTERBERG whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHAEL G. HARTLEY/
Supervisory Patent Examiner, Art Unit 1618

NMW